REMARKS

Claims 58 through 91 find support in the specification at the same location as previously submitted claims so that no new matter is submitted in these claims. Claim 58 finds support at the same location as that for previously submitted claims 12, 34, 48 and 49. Claims 59 through 76 find support in the specification at the same location as previously submitted claims 25 through 42. Claims 77 and 78 find support in the specification at the same location as previously submitted claims 49 and 48 respectively. Claim 79 finds support in the specification at the same location as previously submitted claim 57. Claim 80 finds support in the specification at the same location as previously submitted claim 43 and 44 through 46. Claim 81 finds support in the specification at the same location as previously submitted claim 47. Claims 82 and 83 find support at the same location in the specification as previously submitted claims 48 and 49 respectively. Claims 84 through 90 find support in the specification at the same location as previously submitted claims 50 through 56. Claim 91 finds support in the same location in the specification as previously submitted claim 52 and previously submitted claim 43.

In the office action of December 30, 2004, the specification was questioned in regards to pages 17 and 19. It is respectively submitted that line 12 of page 17 and lines 23 and 29 of page 19 have previously been amended in the amendment filed October 7th when the additional pages of the specification were included. The particular recitations of the recently filed specification and the amended pages are shown below as corrected by the amended recitations.

Amendment to the Specification Page 17 line 12

Example 4

A clear adhesive was made by mixing 689.0 grams (70.3 weight percent) of a polypropyleneoxide with a methyldimethoxysilyl functional group sold under the tradename MS Polymer MAX 601? by Kaneka of Osaka, Japan in a low speed Sigma Blade Lab Mixer from

Teledyne Readco of York, PA keeping the mixer covered to minimize moisture pickup.

Was corrected by amendment to:

Example 4

A clear adhesive was made by mixing 689.0 grams (70.3 weight percent) of a polypropyleneoxide with a methyldimethoxysilyl functional group sold under the tradename MS Polymer MAX 601 by Kaneka of Osaka, Japan in a low speed Sigma Blade Lab Mixer from Teledyne Readco of York, PA keeping the mixer covered to minimize moisture pickup.

Page 19 lines 23 and 29 were

The Sigma Blade Lab Mixer was started on a low speed and the following were added: 220.0 grams (17.3 weight percent) of butyl benzl phthalate sold under the tradename Santicizer 160 by Solutia, Inc. of St. Louis, MO; 550.0 grams (43.3 weight percent) of calcium carbonate sold under the tradename Wingdale White by Imerys of Roswell, GA; 50.0 grams (3.93 weight percent) of titanium dioxide whitener sold under the tradename Tiona RCL-9 by Millenium Inorganic Chemicals Inc.? of Baltimore, MD; 20.0 grams (1.57 weight percent) of fumed amorphous silica filler with a surface area of 200 m^2/gram sold under the tradename Aerosil 200 by Degussa Corporation of Ridgefield Park, NJ; 3.0 grams (0.24 weight percent) of a substituted benzotriazole anti-oxidant sold under the tradename of Tinuvin 327 by Ciba Specialty Chemicals of Tarrytown, NY; 3.0 grams (0.24 weight percent) of a hindered amine light stabilizer anti-oxidant sold under the tradename of Tinuvin P? by Ciba Specialty Chemicals of Tarrytown, NY; and 3.0 grams (0.24 weight percent) of a sterically hindered phenolic anti-oxidant sold under the tradename Irganox 1010 by Ciba Specialty Chemicals of Tarrytown, NY.

Corrected by amendment filed October 7, 2004 to:

> The Sigma Blade Lab Mixer was started on a low speed and the following were added: 220.0 grams (17.3 weight percent) of butyl benzl phthalate sold under the tradename Santicizer 160 by Solutia, Inc. of St. Louis, MO; 550.0 grams (43.3 weight percent) of calcium carbonate sold under the tradename Wingdale White by Imerys of Roswell, GA; 50.0 grams (3.93 weight percent) of titanium dioxide whitener sold under the tradename Tiona RCL-9 by Millenium Inorganic Chemicals Inc. of Baltimore, MD; 20.0 grams (1.57 weight percent) of fumed amorphous silica filler with a surface area of 200 m^2/gram sold under the tradename Aerosil 200 by Degussa Corporation of Ridgefield Park, NJ; 3.0 grams (0.24 weight percent) of a substituted benzotriazole anti-oxidant sold under the tradename of Tinuvin 327 by Ciba Specialty Chemicals of Tarrytown, NY; 3.0 grams (0.24 weight percent) of a hindered amine light stabilizer anti-oxidant sold under the tradename of Tinuvin P by Ciba Specialty Chemicals of Tarrytown, NY; and 3.0 grams (0.24 weight percent) of a sterically hindered phenolic anti-oxidant sold underthe tradename Irganox 1010 by Ciba Specialty Chemicals of Tarrytown, NY.

Disclosure at page 6 lines 25-30 of the application is:

> Preferably, the clear adhesive comprises from about 0.01 to about 50 weight % of filler, more preferably from about 0.01 to about 40 weight % and most preferably from about 5 to about 20 weight %. Preferably, the individual clear filler particles have an average surface area of less than about 250 m^2/gram, more preferably less than about 150 m^2/gram and most preferably less than about 75 m^2/gram.

RESPONSE TO OBJECTIONS UNDER 35 U.S.C. 112

The office action objected to previously submitted claims 53 through 56 under 35 U.S.C. 112, first paragraph. Claim 43 was questioned in regard to a new matter rejection. It is respectfully submitted that the statements recited in the official action regarding the bottom of page 6 of the specification provides support for claim 43. In the CAFC case of *Purdue Pharma L.P. v. Faulding Inc.,* 230F3d 1320 at 1323 (Fed. Circ. 2000) the Court noted that in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claim subject matter at issue. The written description requirement does not require the applicant to describe exactly the subject matter claimed; instead the description must clearly allow persons of ordinary skill in the art to recognize what is claimed. The written description requirement does not require identical descriptions of claimed compounds, but it requires enough disclosure in the patent to show one of skill in this art that the inventor invented the claimed invention.

It is respectfully submitted that the description at the bottom of page 6 of the application clearly notes that the surface area can be less than about 250 more preferably less than about 150 square meters per gram and most preferably less than about 75 square meters per gram. If the surface area can be less than 150 meters square per gram and less than 75 meters square per gram, one skilled in the art would certainly recognize that the surface area can be between 75 and 150 square meters per gram. Therefore, it is respectfully submitted that claim 43 is in compliance with 35 U.S.C. 112, first paragraph. Also it is respectfully submitted that issues similar to this raised for previously submitted claim 49 did not exist with the newly submitted claims.

Previously submitted claims 34-36, 39-41 and 43-57 were rejected under 35 U.S.C. 112, second paragraph as being indefinite. It is respectfully submitted that the newly added claims comply with 35 U.S.C. 112, second paragraph. In regards to the previous objection of claim 34 and claim 58 regarding a surface area limitation for the filler of less than 250 square meters per gram and the dependent claim to the fumed silica being amorphous, fumed silica falls within this range of surface area.

Previously submitted claims 36, 37, 39, 43, 49, 53 and 55 were objected to for the use of improper Markush language. It is respectfully submitted that the MPEP allows for alternative expressions as presented in the pending claims. The MPEP at Section 2173.05(h), Alternative Limitations, indicates that for Markush groups, alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope of clarity of the claims. At section II, it is noted that for "or" terminology, alternative expressions using "or" are acceptable such as "wherein R is a, b, c, or d." Also the following phrases were each held to be acceptable and not in violation of 35 U.S.C. 112, second paragraph in *In Re: Gaubert 524 Fed2d 1222* "made entirely or in part of"; "at least one piece"; and "iron, steel or any other magnetic material". It is respectfully submitted that the terminology in the pending claims complies with MPEP 2173.05(h).

The suggestions of the Examiner in the office action in regards to previously submitted claims 35 and 36 and 39 and 55 have been adopted in the added claims. Also the examiner's suggestions for previously submitted claims 40 and 56 and 43 and 51 and 52 have been considered in drafting the added claims.

RESPONSE TO REJECTION UNDER 35 U.S.C. 102/103(a)

Previously submitted claims 24-51 and 53-57 were rejected under 35 U.S.C. 103(a) as obvious over the product brochure "MS Polymer Silyl of Kaneka Corporation (hereinafter Kaneka reference) in view of the *Staiger, et al* patent (U.S. Patent 5,304,621, hereinafter '621').

It is respectfully submitted that the previously pending claims are unobvious and patentable over the Kaneka reference in view of the '621' patent. There is no teaching or suggestion that the silicone polymers of the '621' patent are in any way equivalent to the polymers of the Kaneka reference other than their end groups. A polymer material is certainly more than just its end group which affects its performance and its properties. Without this teaching or suggestion of equivalence between the polymers, one skilled in the art cannot make even a hypothesis that the end groups disclosed and suggested in the '621' patent perform in any way for the

polymers of the Kaneka reference for an adhesive composition also having filler and dehydrating agent as is claimed in applicant's previously pending and added claims.

Previously submitted claims 24-51 and 53-57 were rejected under 35 U.S.C. 103(a) as obvious over the Kaneka corporation reference in '621' patent further in view of the Bennington patent publication, U.S. 204/0116547A1 (hereinafter '547A1 reference'). It is respectfully submitted that because of the absence of any teaching or suggestion of equivalence between the polymer of the Kaneka reference and the '621" patent, as mentioned above, the pending claims are unobvious and patentable over the combination of references.

Previously submitted claims 24-30, 34, 36-38, 40, 42-50, 53, 54 and 56 were rejected under U.S.C. 35 102(b) as anticipated by or in the alternative under 35 U.S.C. 103(a) as obvious over *Imai et al, U.S. 4,760123*, hereinafter '123 reference'.

The Imai '123 patent' reference is directed to a room temperature curing polyorganosiloxane composition. The polymeric material is a polyorganosilane which is not a carbon based type polymeric material as now claimed in applicant's added claims. In addition, the Imai '123 reference' mentions additional components or additives that might be present which include pigments, thixotropic agents, viscosity controllers for improving handling and extruding processes, a UV-ray intercepting agent, an antifungal agent, a heat resistance improver, an adhesive improver, a flame retarder, etc. There is no mention of a dehydrating additive or agent. Applicant's previously pending and added claims include a dehydrating agent.

Previously submitted claims 24-30, 34, 36-38, 40-50, 53, 54, 56 and 57 were rejected under 35 U.S.C. 103(a) as obvious over Imai et al '123 reference'.

It is respectfully submitted that pending claims are unobvious and patentable over the Imai et al reference '123' for the reasons mentioned above for the difference in the polymeric material and for the reason that there is no teaching of a dehydrating

agent in an adhesive formulation with the filler as claimed in the previously pending and added claims.

Previously submitted claims 24-34, 36-38, 40-51, 53, 54, 56 and 57 were rejected under 35 U.S.C. 102(b) as anticipated by or in the alternative under 35 U.S.C. 103(a) as obvious over the '621 patent' for reasons of record. It is respectfully submitted that for the reasons mentioned above, the difference in polymers between that of the pending claim and the '621 reference' the previously pending and added claims are novel and unobvious and therefor patentable over the references.

The Office Action indicated that claim 52 would be allowable if rewritten or amended to overcome the rejections under 112 in an independent form. Claim 91 is the rewritten, independent form of previously submitted claim 52.

Reconsideration of applicant's currently pending claims are respectfully requested to place the application in condition for allowance or to narrow issues on appeal. The examiner is requested to advise applicant of the disposition of this amendment so that applicant can take the necessary actions to have the allowable claims passed to issuance and to have any other claims reconsidered.

Respectfully submitted,

Date: April 6, 2005

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230 F.3d 1320
230 F.3d 1320, 56 U.S.P.Q.2d 1481
(Cite as: 230 F.3d 1320)

H

Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.
PURDUE PHARMA L.P. and The Purdue Frederick Company, Plaintiffs-Appellants,
v.
FAULDING INC., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co., Defendants-Cross-Appellants,
and
Zeneca Inc., Defendant.
Nos. 99-1416, 99-1433.

DECIDED: Oct. 25, 2000
Rehearing and Rehearing En Banc Denied March 5, 2001. [FN*]

FN* Dyk, Circuit Judge, did not participate in the vote.

Owner of patent claiming methods of treating pain in patients by administering a sustained-release opioid once a day brought infringement action against competitor. After bench trial, the United States District Court for the District of Delaware, Joseph J. Farnan, Jr., J., 48 F.Supp.2d 420, found that competitor had infringed patent but that claims at issue were invalid. Owner appealed, and competitor cross-appealed. The Court of Appeals, Bryson, Circuit Judge, held that: (1) limitation which provided that maximum plasma concentration was to be more than twice the plasma level of the opioid at about 24 hours after its administration was not supported by the disclosure as originally filed; (2) district court properly evaluated written description issue; and (3) district court was not required to defer to findings of patent examiner.

Affirmed.

West Headnotes

[1] Patents ⇐99
291k99 Most Cited Cases
In order to satisfy the patent statute's written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue; nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. 35 U.S.C.A. § 112.

[2] Patents ⇐99
291k99 Most Cited Cases
In order to satisfy the patent statute's written description requirement, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims; inquiry is a factual one and must be assessed on a case-by-case basis. 35 U.S.C.A. § 112.

[3] Patents ⇐324.55(3.1)
291k324.55(3.1) Most Cited Cases
When the question whether a patent satisfies the written description requirement is resolved by a district court sitting as the trier of fact, Court of Appeals reviews the court's decision for clear error. 35 U.S.C.A. § 112.

[4] Patents ⇐99
291k99 Most Cited Cases
Limitation in patent for method of treating patients with sustained-release opioid, which provided that maximum plasma concentration was to be more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, was not supported by specification's description of invention as having a generally flat or substantially flat morphine plasma concentration curve, for purpose of written description requirement, absent evidence that person skilled in the art would interpret term "flat" to be limited to a concentration level ratio less than or equal to two. 35 U.S.C.A. § 112.

[5] Patents ⇐99

291k99 Most Cited Cases
Limitation in patent for method of treating patients with sustained-release opioid, which provided that maximum plasma concentration was to be more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, was not supported by examples in patent in which morphine formulation had claimed ratio, for purpose of written description requirement, where other examples in patent did not have claimed ratio, and there was nothing in patent that would direct skilled artisan to ratio as an important aspect of the invention. 35 U.S.C.A. § 112.

[6] Patents ⇦99
291k99 Most Cited Cases
Patentee's assertion that it claimed narrower range, in patent for method of treating patients with sustained-release opioid, for ratio of maximum plasma concentration to plasma level of opioid at 24 hours after its administration than was disclosed in examples in patent specification was immaterial to whether claims met written description requirement, where specification did not clearly disclose to skilled artisan that ratio was part of invention. 35 U.S.C.A. § 112.

[7] Patents ⇦99
291k99 Most Cited Cases
District court's statement, in finding that patent for method of treating patients with sustained-release opioid did not meet written description requirement, that court viewed examples collectively because there was no way to determine which examples embodied invention, did not establish that court improperly required patentee to identify what was invention and what was not; court was merely noting that it had to view examples collectively because specification did not state that any particular examples pertained to invention recited in amended claims.

[8] Patents ⇦99
291k99 Most Cited Cases
To find that amended patent claims meet written description requirement, support for the invention as defined by those claims must be found in the specification as filed, and the amended claims may not be used to provide that support. 35 U.S.C.A. § 112.

[9] Patents ⇦112.3(1)
291k112.3(1) Most Cited Cases
District court was not required to defer to finding of patent examiner that new claims added to patent application were "supported by the specs," in determining whether claims met written description requirement, as court found that examiner's statement was not persuasive in light of all the evidence in the case. 35 U.S.C.A. § 112.

[10] Patents ⇦112.3(1)
291k112.3(1) Most Cited Cases
Despite deference given to decision of Patent and Trademark Office (PTO) with respect to patentability in district court litigation, in form of presumption of validity that is accorded to issued patents, court was not bound by examiner's finding in ex parte application proceeding that patentee's amended claims were supported by the specification, particularly where court heard extensive evidence on the issue in an adversary hearing, none of which was before the patent examiner. 35 U.S.C.A. § 282.

Patents ⇦328(2)
291k328(2) Most Cited Cases
5,202,128. Cited As Prior Art.

Patents ⇦328(2)
291k328(2) Most Cited Cases
5,478,577. Cited.

Patents ⇦328(2)
291k328(2) Most Cited Cases
5,672,360. Invalid.
***1321** S. Leslie Misrock and Victor N. Balancia, Pennie & Edmonds LLP, of New York, New York, argued for plaintiffs-appellants. With them on the brief was Todd A. Wagner, and Stanton T. Lawrence, III, Pennie & Edmonds LLP, of Washington, DC.

Steven J. Lee, Kenyon & Kenyon, of New York, New York, argued for defendants-cross appellants. With him on the brief were Paul H. Heller, Edward J. Handler, III, Charles A. Weiss, William G. James, II, and Mark I. Koffsky. Of counsel on the brief was E. Brendan Magrab, Faulding Inc., of Elizabeth, New Jersey. Of counsel were Jack B. Blumenfeld, and Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, of Wilmington, Delaware.

Before PLAGER, Circuit Judge, SMITH, Senior Circuit Judge, and BRYSON, Circuit Judge.

BRYSON, Circuit Judge.

Purdue Pharma L.P. and The Purdue Frederick Company (collectively Purdue) own U.S. Patent No. 5,672,360 (the '360 patent), which is drawn to methods of treating pain in patients by administering ***1322** an opioid, such as morphine, once a day. Purdue brought a patent infringement suit against Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (collectively Faulding) in the United States District Court for the District of Delaware. After a bench trial, the district court found that Faulding had infringed the asserted claims of the '360 patent but that the claims were invalid. Purdue appeals from the finding of invalidity, and Faulding cross-appeals from the finding of infringement. We uphold the court's ruling invalidating the asserted claims of the '360 patent; we do not reach Faulding's cross-appeal on the issue of infringement.

I

In 1984 Purdue introduced a sustained-release, twice-a-day oral morphine formulation. Sustained-release formulations represent a significant advance over immediate-release morphine formulations because immediate-release formulations need to be administered every four hours, a schedule that interferes with the patient's sleep and subjects the patient to cycles of pain that are difficult to control.

After its success with its twice-a-day formulation, Purdue sought to develop a sustained-release oral morphine formulation that would need to be administered only once a day. The work of its researchers initially led to the issuance of U.S. Patent No. 5,478,577 (the '577 patent), which discloses a once-a-day formulation exhibiting a rapid initial rise in the opioid concentration in the patient's blood.

During the same period, Faulding was developing long-lasting opioid anti-pain formulations as well. In 1996, Faulding began marketing its oral sustained-release morphine formulation in the United States under the trade name Kadian. The package insert accompanying Kadian states that it may be administered either once or twice a day.

Shortly after Faulding began selling Kadian in this country, Purdue brought suit against Faulding and Zeneca Inc., alleging that the manufacture, sale, and use of Kadian as a once-a-day morphine formulation infringed the '577 patent. At the time the suit was filed, the inventors of the '577 patent had pending before the Patent and Trademark Office U.S. Patent Application Serial No. 08/578,688 (the '688 application), which claimed priority to the application that led to the '577 patent.

While the litigation over the '577 patent was pending, Purdue's counsel canceled the pending claims of the '688 application and amended the application to add all new claims. The application was allowed as amended, and it issued as the '360 patent on September 30, 1997. No art rejections were made against the issued claims. The only prosecution history is contained in a handwritten interview summary in which the examiner stated that the new claims are supported by the specs.

Purdue asserts that the once-a-day formulation described in the treatment method of the '360 patent , which results in a substantial fluctuation in the opioid concentration in the patient's blood between the maximum concentration level and the concentration level at the end of the 24-hour dosage period, was contrary to the prevailing view at the time that sustained-release formulations should produce minimal fluctuations in the opioid concentration level during the dosing interval. That aspect of the invention is reflected in each of the claims of the '360 patent, including claims 2, 4, and 11, the three asserted claims at issue in this case. Claims 1 and 9, on which the three asserted claims depend, both contain a limitation requiring that the maximum plasma concentration of the opioid be more than twice the plasma level of the opioid 24 hours after administration of the drug. The pertinent claims of the ' 360 patent at issue in this case read as follows:

> 1. A method of effectively treating pain in humans, comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an ***1323** opioid analgesic or salt thereof which upon administration provides a time to maximum

plasma concentration (Tmax) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (Cmax) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.
2. The method of claim 1, wherein the Tmax occurs in about 2 to about 8 hours after oral administration of said dosage form.
4. The method of claim 1, wherein said opioid analgesic is morphine sulfate.
9. A method of effectively treating pain in humans, comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which at steady-state provides a time to maximum plasma concentration (Tmax) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (Cmax) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.
11. The method of claim 9, wherein said opioid analgesic is morphine sulfate.

Shortly after the '360 patent issued, Purdue amended the complaint in the pending litigation against Faulding and Zeneca by dropping its claims under the '577 patent and asserting infringement of the '360 patent. Faulding and Zeneca asserted various counterclaims, including non-infringement and invalidity, and a bench trial was held on liability. During trial, the district court dismissed the claims against Zeneca. Following the trial, the court held that Faulding's production and sale of Kadian infringed the asserted claims of the '360 patent, but that the claims were invalid because they lacked the written description required by 35 U.S.C. § 112, first paragraph. The court then entered final judgment on the tried issues under Fed.R.Civ.P. 54(b).

II

The validity issue in this case is whether the limitation a maximum plasma concentration (Cmax) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form [C24] was adequately described in the disclosure of the '688 application as originally filed. The trial court found that it was not.

[1][2][3] In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue. *See Fujikawa v. Wattanasin,* 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must ... convey with reasonable clarity to those skilled in the art that ... [the inventor] was in possession of the invention. *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed.Cir.1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. *Waldemar Link GmbH & Co. v. Osteonics Corp.,* 32 F.3d 556, 558, 31 UPSQ2d 1855, 1857 (Fed.Cir.1994). That inquiry is a factual one and must be assessed on a case-by-case basis. *See Vas-Cath,* 935 F.2d at 1561, 19 USPQ2d at 1116 (Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.). When the question whether a patent satisfies the written description requirement is resolved by a district court sitting as the trier of fact, we review the court's decision for clear error. *See Tronzo v. Biomet, Inc.,* 156 F.3d 1154, 1158, 47 USPQ2d 1829, 1832 (Fed.Cir.1998); ***1324***Gentry Gallery, Inc. v. Berkline Corp.,* 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1502 (Fed.Cir.1998).

Purdue contends that the district court made various legal errors in its analysis of the written description issue and that its factual finding on that issue was clearly erroneous. Turning first to the district court's factual analysis, we conclude that the court's finding on the written description issue did not constitute clear error.

A

The district court found that the specification of the '360 patent fails to convey that the Cmax/C24 limitation was encompassed within Purdue's original invention. Purdue attacks that finding on several fronts, but its arguments are unpersuasive.

1

[4] Purdue first argues that the Cmax/C24 limitation is supported by the portion of the specification that describes the invention as not having a generally flat or substantially flat morphine plasma concentration curve. The passage of the specification on which Purdue relies reads as follows:

> The state-of-the-art approach to controlled release opioid therapy is to provide formulations which exhibit zero order pharmacokinetics and have minimal peak to trough fluctuation in opioid levels with repeated dosing. This zero order release provides very slow opioid absorption, and a generally flat serum concentration curve over time. A flat serum concentration curve is generally considered to be advantageous because it would in effect mimic a steady-state level where efficacy is provided but side effects common to opioid analgesics are minimized....
>
> It has now been surprisingly discovered that quicker and greater analgesic efficacy is achieved by 24 hour oral opioid formulations which do not exhibit a substantially flat serum Concentration curve, but which instead provide a more rapid initial opioid release so that the minimum effective analgesic concentration can be more quickly approached in many patients who have measurable if not significant pain at the time of dosing.... Also surprising and unexpected is the fact that while the methods of the present invention achieve quicker and greater analgesic efficacy, there is not a significantly greater incidence in side effects which would normally be expected as higher peak plasma concentrations occur.

'360 patent, col. 5, ll. 24-55. The district court disagreed with Purdue's argument that the phrase formulations which do not exhibit a substantially flat serum Concentration curve refers to the Cmax/C24 ratio of more than two that was added in the amended claims. Instead, the court concluded that the term refers to the feature of rapid opioid release that was recited in the original claims of the application and was described in the specification as critical to the invention. The court's finding is supported by the context in which the statement appears, and it is consistent with the claims as originally filed, which defined the formulation as providing an initially rapid rise ... by providing an absorption half-life [*i.e.,* the time required for one-half of the absorbable opioid to be absorbed into the plasma] from about 1 to 8 hours.

In addition to finding that the substantially flat language in the specification did not refer to the Cmax/C24 limitation, the trial court found that even if that language were understood to relate to the fluctuation in opioid concentration in the blood between the maximum concentration level and the concentration level after 24 hours, one skilled in the art would not understand the term substantially flat to mean a fluctuation of 100% or less.

At trial, Purdue offered expert testimony that the term flat is understood in the field to mean a fluctuation of 100% or less in the concentration of opioid between the maximum level and the level after 24 hours, *i.e.,* a Cmax/C24 ratio of two or less. ***1325** The court, however, was unpersuaded. As the court explained, one of Purdue's experts, Dr. Goldenheim, described another sustained-release morphine formulation, Roxanol SR, as having a flat serum concentration curve, even though he acknowledged that it has a fluctuation of over 100%. In addition, the court found that the publications relied upon by Purdue did not substantiate Purdue's assertion that flat means fluctuations of 100% or less. Moreover, the court stated that even if it accepted Purdue's argument that flat means a fluctuation of 100% or less, the use of the modifier "substantially" in the specification, indicates that the word "flat" as used in the '360 patent specification, does not even refer to the precise quantification urged by Purdue.

One of the publications Purdue relied on at trial was International Publication Number WO 94/22431, on which Kabi Pharmacia AB was the applicant. The Kabi application provides pharmacokinetic profiles for two different morphine formulations, CR-A and CR-B. The trial court found that for the CR-A formulation the Cmax level was more than twice as great as the C24 level, and that for the CR-B formulation the Cmax level was less than twice as great as the C24 level. Nonetheless, the Kabi application described both formulations as having low fluctuations. The court therefore found that the Kabi application fails to support Purdue's contention that one skilled in the art understands "flat" to mean fluctuations of less than 100%.

Purdue argues that Kabi's CR-A is a twice-a-day formulation and that the court's reliance on that formulation was therefore misplaced. As noted by Faulding, however, the data in the Kabi application was based on the administration of a single dose of morphine. For that reason, the court was not mistaken in relying on the description of the Cmax/C24 ratio for the CR-A formulation in concluding that the Kabi application fails to support Purdue's argument that one skilled in the art would interpret substantially flat to mean a Cmax/C24 ratio of two or less.

Purdue also argues that the trial court was confused with respect to Dr. Goldenheim's testimony regarding Roxanol SR, which Dr. Goldenheim characterized as having a flat profile. Purdue argues that Roxanol SR is approved only as an eight-hour formulation and that the Cmax/C8 ratio of Roxanol SR is less than 2. On cross-examination, however, Dr. Goldenheim was asked to calculate a Cmax/C12 ratio for Roxanol SR from an article containing pharmacokinetic studies of the drug. From the data presented in the paper, Dr. Goldenheim determined that the Cmax/C12 ratio for Roxanol SR is greater than two, and he characterized that Cmax/C12 ratio as pretty flat.

That evidence is meaningless, Purdue asserts, because Roxanol is not described as being approved for twice-a-day administration. Dr. Goldenheim's testimony on cross-examination, however, related to the morphine concentration in the Roxanol SR formulation after 12 hours, and the district court reasonably interpreted Dr. Goldenheim's testimony as a concession that a Cmax/C12 ratio greater than two would still be considered flat. From that evidence, the district court permissibly concluded that a person skilled in the art would not necessarily interpret the term flat to be limited to a concentration level ratio less than or equal to two.

Finally, Purdue asserts that the trial court erroneously failed to consider the teachings of the Morella patents. Those patents, Purdue contends, establish that by 1993 it was understood in the field that a flat pharmacokinetic profile constituted a profile having fluctuations of 100% or less. For example, Purdue argues, U.S. Patent No. 5,202,128, to Morella et al. states that an advantage of the morphine formulations of the invention is that the peak-to-trough variation will be between 60% and 100%, which has been described as a flat plasma morphine concentration time profile. Purdue, however, does not point to anything in the Morella patents that suggests that if the peak-to-trough variation is greater ***1326** than 100%, the concentration profile would not be considered flat. The Morella patents therefore do not in any way undermine the district court's finding that a person of ordinary skill in the art would not understand the term substantially flat to denote a Cmax/C24 ratio of two or less.

2

[5] Purdue argues that even if the passage from the specification referring to the substantially flat serum Concentration curve does not provide the required written description for the Cmax/C24 ratio recited in the claims, the examples set forth in the patent provide adequate support for that limitation. Purdue relies on Example 1 (fed and fasted) and Example 3 (fed only) to support the claimed limitation, as the morphine formulation in both examples resulted in a Cmax/C24 ratio greater than two.

The district court rejected Purdue's argument, pointing out that the specification also contains examples in which the Cmax/C24 ratio is less than two and that nothing in the specification indicates to the skilled artisan which examples embody the claimed invention and which do not. We conclude that the district court did not commit clear error in finding that the examples do not provide sufficient support for the Cmax/C24 limitation.

The specification sets forth seven examples. Values for Cmax and C24 are provided for only the first three. Other pharmacokinetic data are provided as well, and morphine concentrations are provided for times other than 24 hours after administration of the drug. Although the examples provide the data from which one can piece together the Cmax/C24 limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the Cmax/C24 ratio. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the Cmax/C24 ratio as an aspect of the invention.

The case of *In re Ruschig,* 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ 118 (1967), is instructive here. In that case our predecessor court affirmed the holding of the Patent Office Board of Appeals that one of the claims, adopted for purposes of interference, was not supported by the disclosure. The claim at issue in that case was directed to a single compound. The applicants argued that, although the compound itself was not disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The *Ruschig* court rejected that argument, stating that

> [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared--or have not yet been made, which is more like the case here--to be confronted simply by a large number of unmarked trees. We are looking for blaze marks which single out particular trees. We see none.

Id. at 994-95, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122. Although this case differs from *Ruschig* in that what was disclosed in *Ruschig* was a genus encompassing potentially half a million compounds, the rationale applies equally to this case, in which the disclosure of the '360 patent discloses a multitude of pharmacokinetic parameters, with no blaze marks directing the skilled artisan to the Cmax/C24 ratio or what value that ratio should exceed. *See id.* at 994, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122 (Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required.). As *Ruschig* makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree ***1327** must be in the originally filed disclosure. *See id.* at 994-95, 54 C.C.P.A. 1551, 379 F.2d 990, 154 USPQ at 122; *Fujikawa,* 93 F.3d at 1570-71, 39 USPQ2d at 1905; *Martin v. Mayer,* 823 F.2d 500, 505, 3 USPQ2d 1333, 1337 (Fed.Cir.1987) (It is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.") (quoting *Jepson v. Coleman,* 50 C.C.P.A. 1051, 314 F.2d 533, 536, 136 USPQ 647, 649-50 (1963)). Under that standard, we conclude that the district court did not commit clear error in finding that nothing in the '688 application "necessarily" ... described the later claimed subject matter of the '360 patent. *In re Daniels,* 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed.Cir.1998).

In the case of the '360 patent, there is nothing in the written description of Examples 1 and 3 that would suggest to one skilled in the art that the Cmax/C24 ratio is an important defining quality of the formulation, nor does the disclosure even motivate one to calculate the ratio. For example, the description of Example 1 states that

> [p]lasma morphine concentrations were used for calculation of phamacokinetic parameters including: (a) absorption and elimination rates; (b) area under the curve (AUC); (c) maximum plasma concentration (Cmax); (d) time to maximum plasma concentration [(]Tmax); (e) T1/2 (elimination).

'360 patent, col. 16, ll. 24-29. Figure 9 of the patent graphically represents the mean morphine plasma concentration-time profile for Examples 1 and 2, as well as for the control formulation, MS-Contin. In discussing Figure 9, the disclosure merely states that it can be seen that the formulation of Example 1 attains a higher and earlier Cmax but a slightly lower extent of morphine absorption than the formulation of Example 2. *Id.* at col. 21, ll. 8-11.

These statements and the calculation of the listed pharmacokinetic parameters are consistent with how the inventors characterize the invention, as the specification states earlier that inventive sustained release once-a-day formulations may be characterized by the fact that they are designed to provide an initially rapid rate of rise in the plasma concentration of said opioid characterized by providing an absorption half-life from about 1 to about 8 hours, '360 patent, col. 6, ll. 1-5, and also that the inventive formulations may be further characterized by having a surprisingly fast time to peak drug concentration (*i.e.,* tmax), *id.* at col. 6, ll. 10-12. As can be seen from these excerpts from

the specification, however, there is nothing in the written disclosure as originally filed directing the skilled artisan to the Cmax/C24 ratio.

What the '360 patentees have done is to pick a characteristic possessed by two of their formulations, a characteristic that is not discussed even in passing in the disclosure, and then make it the basis of claims that cover not just those two formulations, but any formulation that has that characteristic. This is exactly the type of overreaching the written description requirement was designed to guard against. *See Vas-Cath,* 935 F.2d at 1561, 19 USPQ2d at 1115 (Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.) (quoting *Rengo Co. v. Molins Mach. Co.,* 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir.1981)).

3

[6] Purdue characterizes this case as one in which, at bottom, the applicants claimed less than they disclosed. Using the data from Examples 1 and 3, the skilled artisan can establish a range for the Cmax/C24 ratio of 1.28 to 3.43. Thus, according to Purdue, the claim limitation requiring Cmax/C24 to be greater than two is narrower than the range disclosed in the specification. Purdue asserts that it did ***1328** not consider claims in which the Cmax/C24 ratio was less than two to be patentable in light of the prior art, and that its willingness to settle for claims narrower than the invention it disclosed does not create a written description problem.

Because the specification does not clearly disclose to the skilled artisan that the inventors of the '360 patent considered the Cmax/C24 ratio to be part of their invention, it is immaterial what range for the Cmax/C24 ratio can be gleaned from the examples when read in light of the claims. There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the claims carved out a patentable portion.

B

Apart from the asserted factual flaws in the district court's analysis, Purdue contends that the trial court committed several errors of law that affected the court's analysis of the written description issue and require reversal. We have examined each of the claimed legal errors and conclude that the district court did not commit any error of law that had a material effect on the court's judgment.

1

[7] First, Purdue argues that the district court applied the wrong legal test for determining whether the written description requirement was satisfied. Purdue acknowledges that the district court recited the correct test, as set forth in this court's decision in the *Vas-Cath* case, *supra,* but argues that the court actually applied a different test--one that was specifically rejected in *Vas-Cath.* In particular, Purdue relies on a statement in the district court's opinion in which the court commented that viewing the examples collectively, as the Court believes must be done because there is no way to determine which embody the invention and which do not, the examples illustrate a range between 1.48 and 3.43. That comment, according to Purdue, shows that the district court required the specification to set forth what the invention is and what it is not, which is not the correct test under the written description requirement.

Purdue has misinterpreted the quoted passage from the district court's opinion. The court did not insist that the examples identify exactly what constitutes the claimed invention and what does not; instead, the court simply noted that it had to view all of the examples collectively because the specification did not state that any particular examples pertained to the invention that was recited in the amended claims. Under the circumstances, it was entirely appropriate for the district court to view all of the examples together in its effort to determine whether the disclosure as filed contained a sufficient written description of the invention; indeed, that approach was necessary in order for the court to determine that the inventor had possession at that time of the later claimed subject matter. *Vas-Cath,* 935 F.2d at 1563, 19 USPQ2d at 1116.

Purdue makes the related contention that the district court did not view the disclosure as a whole in determining whether the written description requirement was satisfied. Again, we read the

district court's opinion differently. Although the district court discussed the examples and the text of the specification separately, it is clear from the court's opinion that it concluded that the specification as a whole did not support the asserted claims of the '360 patent; there is nothing in the court's opinion suggesting that the court considered that any one segment of the specification, standing alone, had to provide the full support for the amended claims.

2

[8] Purdue next argues that the district court committed legal error by looking to the written description portion of the patent, rather than the claims, to define the invention for purposes of the written description analysis. The district court made no error in this regard. The ***1329** court noted that it must necessarily look to the claim language to determine if the specification supports what is now claimed, and it further explained that it could not consider the amended claims themselves, which did not appear in the application as filed, to show that at the time of filing the inventor was in possession of what is now claimed. We interpret those remarks as simply articulating the correct legal principles that the amended claims define the invention, that the support for the invention must be found in the specification as filed, and that the amended claims could not be used to provide that support.

3

[9] Finally, Purdue contends that the district court improperly disregarded the findings of the examiner, who stated in an interview summary at the time the amended claims were added to the application that the new claims are supported by the specs. Purdue argues that the district court should have deferred to the examiner's finding on that issue and that the district court failed to do so because the court improperly regarded the written description issue to be an issue of law rather than an issue of fact.

It is true that the district court at one point in its opinion characterized validity as an issue of law. Notwithstanding that isolated statement, the court's lengthy and thorough opinion makes it abundantly clear that the court understood that the question whether the written description requirement was satisfied is a question of fact. Moreover, the district court expressly addressed the examiner's statement on which Purdue relies and found it insufficient on the merits to carry the day for Purdue. The court explained that it did not regard the examiner's cryptic statement as directly applicable to the written description requirement but added that even if the examiner's statement was directed to the written description requirement, any deference due to the Patent Examiner has been overcome by Faulding's clear and convincing evidence that the specification does not support the asserted claims of the '360 Patent. Thus, the court rejected the examiner's statement on which Purdue relies not because of a misconception about the nature of the issue before it, but because the court did not find the examiner's statement persuasive in light of all the evidence in the case.

[10] Relying on the Supreme Court's decision in *Dickinson v. Zurko,* 527 U.S. 150, 119 S.Ct. 1816, 144 L.Ed.2d 143, 50 USPQ2d 1930 (1999), Purdue makes the related argument that the district court should have sustained the examiner's decision on the written description issue as long as it was supported by substantial evidence. The short answer to that argument is that this was an infringement action that originated in the district court, not an appeal from a decision of the Patent and Trademark Office Board of Appeals and Interferences, which was at issue in *Zurko.* The Administrative Procedure Act standard of review adopted in *Zurko* therefore has no application here. To be sure, as we have noted, the decision of the Patent and Trademark Office with respect to patentability is accorded deference in district court litigation, deference that takes the form of the presumption of validity that is accorded to issued patents under 35 U.S.C. § 282. *See Fromson v. Advance Offset Plate, Inc.,* 755 F.2d 1549, 1555, 225 USPQ 26, 31 (Fed.Cir.1985). The court, however, was not bound by the examiner's finding in the *ex parte* application proceeding that the new claims were supported by the specification, particularly in light of the fact that the court heard extensive evidence on the issue in an adversary hearing, none of which was before the patent examiner.

III

Because we have upheld the district court's

determination that the asserted claims of the '360 patent are invalid, it is unnecessary to address Faulding's cross-***1330** appeal from the district court's finding of infringement.

AFFIRMED.

230 F.3d 1320, 56 U.S.P.Q.2d 1481

Briefs and Other Related Documents (Back to top)

. 2001 WL 34119564 (Appellate Brief) Brief in Opposition to Petition for Rehearing (Feb. 06, 2001)Original Image of this Document (PDF)

. 1999 WL 33630816 (Appellate Brief) Reply Brief for Defendants-Cross Appellants Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (Dec. 06, 1999)Original Image of this Document (PDF)

. 1999 WL 33630794 (Appellate Brief) Reply Brief for Plaintiffs-Appellants, Purdue Pharma L.P. and the Purdue Frederick Company (Nov. 12, 1999)Original Image of this Document (PDF)

. 1999 WL 33630795 (Appellate Brief) Brief for Defendants-Cross Appellants Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., and Purepac Pharmaceutical Co. (Sep. 28, 1999)Original Image of this Document (PDF)

. 1999 WL 33630793 (Appellate Brief) Brief for Plaintiffs-Appellants, Purdue Pharma L.P. and the Purdue Frederick Company (Aug. 16, 1999)Original Image of this Document with Appendix (PDF)

. 99-1433 (Docket)
(Jun. 10, 1999)

. 99-1416 (Docket)
(Jun. 01, 1999)

END OF DOCUMENT

524 F.2d 1222.
524 F.2d 1222, 187 U.S.P.Q. 664
(Cite as: 524 F.2d 1222)

C

United States Court of Customs and Patent Appeals.
Application of Edgar Gustave GAUBERT.
Patent Appeal No. 75-574.

Nov. 13, 1975.

Proceeding in the matter of an application for a patent. The Board of Appeals of United States Patent Office, serial No. 219,932, affirmed decision of primary examiner rejecting as unpatentable all of the involved claims, and applicant appealed. The United States Court of Customs and Patent Appeals, Almond, Senior Judge, held that although somewhat unconventional, reasons of appeal were sufficient to alert solicitor that applicant was appealing rejection under specified statutes, that the device, i. e., a rotor-stator structural combination for use in electric generator or motor, was improperly rejected as lacking utility by reason of being inoperative, that specification was sufficient to enable one skilled in the art to make and use the invention and that claims were not vague and indefinite since they accurately determined boundaries of protection involved.

Reversed.

West Headnotes

[1] Patents ⚿113(4)
291k113(4) Most Cited Cases
Purpose of the reasons of appeal in a patent case is to alert the parties to the issues before the court.

[2] Patents ⚿113(4)
291k113(4) Most Cited Cases
Although somewhat unconventional, reasons of appeal from decision of patent and trademark office affirming rejections of claims in patent application were not deficient for failure to cover each ground of rejection expressly where they were sufficient to alert the solicitor that applicant was appealing the rejection of the claims under specified statutes and there was no indication that solicitor was misled.

[3] Patents ⚿46
291k46 Most Cited Cases
Before rejecting claims as lacking utility by reason of being inoperative the patent and trademark office must do more than merely question operability, it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability. 35 U.S.C.A. § 101.

[4] Patents ⚿49
291k49 Most Cited Cases
When there are several methods for producing a desired effect, including obvious and reasonable alternatives, a mere showing of the nonuse of a disclaimed alternative is not sufficient to show inoperability. 35 U.S.C.A. § 101.

[5] Patents ⚿46
291k46 Most Cited Cases
Claims 1 and 2 of application to patent invention consisting of rotor-stator structural combination for use in an electric generator or motor, with rotor being pair of horseshoe magnets fastened together at their bases, on which was wrapped a coil of wire having its ends connected to a conventional commutator or slip ring, and with stator member being a pair of oppositely disposed horseshoe magnets placed with free ends facing and adjoining free ends of the rotor magnets, were improperly rejected as lacking utility by reason of being inoperative. 35 U.S.C.A. § 101.

[6] Patents ⚿46
291k46 Most Cited Cases
Where in abstract of specification applicant for patent for invention consisting of rotor-stator structural combination for use in an electric generator or motor stated that it was "possible" to neutralize eddy currents with the invention and in request for reconsideration stated that he had succeeded in eliminating eddy currents while retaining useful currents but the appealed claims did not recite that the apparatus alleviated eddy currents, failure of the apparatus to solve the eddy currents problem was not dispositive of question of operability of the claimed subject matter, i. e.,

whether the device lacked utility by reason of being inoperative. 35 U.S.C.A. § 101.

[7] Patents ⇦101(5)
291k101(5) Most Cited Cases
Specifications for claimed invention involving rotor-stator structural combination for use in an electric generator or motor were sufficiently detailed to enable one skilled in the art to make and use the claimed invention; hence, rejection of claim for failure to satisfy statutory enabling requirement was improper. 35 U.S.C.A. § 112.

[8] Patents ⇦113(1)
291k113(1) Most Cited Cases
Where two claims submitted after decision of Patent and Trademark Board of Appeals affirming rejection of all claims were not considered by Board they could not be reviewed or considered on appeal to Court of Customs and Patent Appeals.

[9] Patents ⇦101(6)
291k101(6) Most Cited Cases
Although expressions in claims of the alleged invention, i. e., a rotor-stator structural combination for use in an electric generator or motor, were somewhat ungainly, rejection of claims as being vague and indefinite was improper where the specification nevertheless accurately determined the boundaries of the protection involved. 35 U.S.C.A. § 112.
***1223** Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents, R. V. Lupo, Associate Solicitor, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, RICH, BALDWIN and MILLER, Associate Judges, and ALMOND, Senior Judge.

ALMOND, Senior Judge.

This is an appeal from the decision of the Patent and Trademark Office (PTO) Board of Appeals affirming the rejections of claims 1 and 2, all of the claims in application serial No. 219,932 filed January 24, 1975, entitled "Rotors and Stators of Electric Generators and Motors." The rejections were made under 35 U.S.C. ss 101 and 112, first and second paragraphs. We reverse.

The Invention

Appellant's invention is a rotor-stator structural combination for use in an electric generator or motor.

The rotor of the preferred embodiment is a pair of horseshoe magnets fastened together at their bases. Around the bases is wrapped a coil of wire with its ends connected to a conventional commutator or slip ring.

The stator member is a pair of oppositely disposed horseshoe magnets placed with the free ends facing and adjoining the free ends of the rotor magnets. Each stator magnet has a north pole facing the south pole of a rotor magnet and a south pole facing the north pole of the same rotor magnet. As the rotor turns, the north oriented arms of the rotor magnets are in the same plane with the south oriented arms of the stator magnets, and the south oriented arms of the rotor magnets are coplanar with the north oriented arms of the stator magnets. Additional coils may be wrapped around the stator magnets.

Claims 1 and 2, the only claims on appeal, are set forth below:

1. A rotor member made entirely or in part of one or several assembled pieces of iron, steel or any other magnetic material and to be used as a part of electric generators and motors and which comprises one or more horseshoe type or U shape type magnets or electromagnets with their magnetic poles placed side by side and parallel with the shaft of the rotor but separated from each other by one or more annular coils of wire made of electrical conducting material and wound on the cylindric root circumference of the rotor.
2. A stator member made entirely or in part of one or several assembled pieces of iron, steel or any other magnetic material and to be used as a part of electric generators or motors and which comprises one or more horseshoe type or U shape type magnets or electromagnets with their magnetic poles placed side by side and parallel with the shaft of the rotor but separated ***1224** from each other by one or more annular coils of wire made of electrical conducting material.

The Rejections

The rejections under 35 U.S.C. s 101 and 35 U.S.C. s 112, first paragraph, were that the device lacks utility by virtue of being inoperative and that

the disclosure is not enabling. In support of these rejections, the board cited a section of University Physics [FN1] showing a generator of the type in which the rotor coil rotates about an axis perpendicular to and through a stationary magnetic field. The board explained that the specification failed to describe a device of the type shown in University Physics, raised some questions about construction details and operation, and concluded the device was inoperative and inadequately disclosed. The claims were further rejected as indefinite under 35 U.S.C. s 112, second paragraph.

FN1. F. Sears & M. Zemansky, University Physics, 610-13 (2d ed. 1955).

OPINION

The Reasons of Appeal

[1][2] The solicitor's memorandum submits that the reasons of appeal fail to cover each ground of rejection expressly. The purpose of the reasons of appeal is to alert the parties to the issues before the court. In In re Castner, 518 F.2d 1234 (CCPA 1975), this court adopted the view of the concurring opinion of Judge Rich in In re LePage's Inc., 312 F.2d 455, 467, 50 CCPA 852, 868 (1963), where he stated:

> Looking upon the reasons of appeal as in essence a pleading, they should be considered sufficient if they get the parties and the issues and a sufficient record into court in such fashion that the court can deal with the issues. The business of modern courts is to decide issues and settle disputes and not to make life unnecessarily difficult for litigants with no gain to itself.

Although somewhat unconventional, due perhaps in part to the pro se nature of the case, the reasons of appeal are sufficient to alert the solicitor that appellant is appealing the rejection of claims 1 and 2 under 35 U.S.C. s 101 and 35 U.S.C. s 112, first and second paragraphs. There is no indication that the solicitor was misled.

The Rejection Under 35 U.S.C. s 101

[3][4][5][6] Turning now to the merits, the Patent and Trademark Office has rejected both claims under 35 U.S.C. s 101 [FN2] asserting that appellant's device lacks utility by reason of being inoperative.

FN2. 35 U.S.C. s 101. Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In In re Langer, 503 F.2d 1380, 1391-92 (CCPA 1974), we set forth the test for a prima facie case of lack of utility saying:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of s 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope. Assuming that sufficient reason to question the statement of utility and its scope does exist, a rejection for lack of utility under s 101 will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the statement of utility and its scope as found in the specification are true. (Emphasis ours.)

Accordingly, the PTO must do more than merely question operability it must set forth factual reasons which would lead ***1225** one skilled in the art to question the objective truth of the statement of operability.

Electromotive force is induced in a coil which is subjected to a changing magnetic flux field. This condition can be brought about in several ways by spacially moving the coil in a stationary, constant flux field as University Physics illustrates, by spacially moving a constant magnetic flux field relative to a stationary coil, by varying the magnitude of a magnetic flux field passing along the axis of a stationary coil, just to name a few.

It is clear from the specification that appellant's device does not involve moving the rotor coil with respect to the magnetic flux field, i. e. the method illustrated by University Physics. The specification states:

> My method used to generate an electric current is very different from the method used in the

> conventional generators in which the electrical conducting wires of the rotor winding must change position with respect to the magnetic lines of force and cut them while in my invention it is the magnetic core of the rotor with its projections which does the cutting of the lines of force.

So rotation of the rotor does not cause the coil to cut a magnetic flux; rather, the rotation causes oscillations in the magnetic flux passing along the iron core (horseshoe magnets) of the rotor coil. The oscillations in magnetic flux result from the cyclic changes in the spacing of the rotor and stator magnets.

The PTO has shown only that the coil does not cut stationary flux lines as it rotates. Because this is not the only way to generate electricity, this fails to establish that the conditions for generating electric energy are absent. When there are several methods for producing the desired effect, including obvious and reasonable alternatives, a mere showing of the non-use of a disclaimed alternative is not sufficient to show inoperability.

Thus the facts relied upon are insufficient, in view of appellant's disclosure, to support the rejection under 35 U.S.C. s 101 for lack of operability of the claimed invention.

The board found "the solution proposed by appellant for the eddy current problem questionable." This comment was apparently based on the abstract of the specification which, we note, says that it is "possible" to neutralize eddy currents [FN3] with the invention; and on appellant's statement in his request for reconsideration, namely: "I therefore succeeded in eliminating the eddy currents while retaining the useful current . . ." However, the appealed claims do not recite that the apparatus alleviates eddy currents. Thus, failure of the apparatus to solve the eddy current problem is not dispositive of the question of operability of the claimed subject matter.

> FN3. Eddy currents are set up in a conductor by variation of an applied magnetic field resulting in power loss and a reduction of magnetic flux.

Since there has been no showing that the basic conditions necessary for a generator/motor are absent, the rejection under 35 U.S.C. s 101 is reversed.

The Rejection Under 35 U.S.C. s 112, First Paragraph

[7] With regard to the rejection of claims 1 and 2 under 35 U.S.C. s 112, first paragraph,[FN4] we set forth the following test for satisfying the enablement requirement of 35 U.S.C. s 112, first ***1226** paragraph, in Martin v. Johnson, 454 F.2d 746, 751, 59 CCPA 769, 775 (1972):

> FN4. 35 U.S.C. s 112. Specification.
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

> To satisfy s 112, the specification disclosure must be sufficiently complete to enable one of ordinary skill in the art to make the invention without undue experimentation, although the need for a minimum amount of experimentation is not fatal. . . . Enablement is the criterion, and every detail need not be set forth in the written specification if the skill in the art is such that the disclosure enables one to make the invention. (Citations omitted.)

The board first questioned how the coil is wound on the rotor. We find appellant's specification describes the coil as "annular" windings "made on the cylindric root circumference of the rotor." Webster's Seventh New Collegiate Dictionary (1965) defines "root" as:

> a: the lower part: base b: the part by which an object is attached to something else . . . .

In an H-shaped rotor, formed by connecting two U-shaped elements about a shaft, a person having ordinary skill in the art would have no trouble determining that the root must be the cross bar of the H the base to which the four arms are attached securing the whole assembly to the shaft. The root

circumference is the cylinder which defines the exterior surface of the cross bar. Hence, a coil formed on the cylindric root circumference of the rotor is wound with its axis along the shaft and each loop virtually in a plane perpendicular to the shaft.

Second, the board questioned the nature of the commutator structure. Given that an electromotive force is induced in the rotor coil, we do not foresee one skilled in the art encountering any difficulty in drawing this energy off by using conventional techniques. The board set forth no basis for suspecting such technical difficulties. Conversely, we see no technical problems in supplying electric energy to the rotor coil to cause the device to function as a motor.

Last, the board questioned whether the materials are laminar. Appellant states that the invention "will increase the possibility of using solid material instead of the very expensive laminates." This choice of construction appears to be a matter of preference going to the efficiency, not the operability, of the resultant device. We see no reason why laminations would be required for operability nor any reason why laminations would make the device inoperative.

Thus, the specification is sufficiently detailed to enable one skilled in the art to make and use the claimed invention and the rejection under 35 U.S.C. s 112, first paragraph, is reversed.

The Rejection Under 35 U.S.C. s 112, Second Paragraph

[8][9] Claims 1 and 2 were further rejected under 35 U.S.C. s 112, second paragraph, [FN5] as being vague and indefinite. Claims 3 and 4, submitted after the board's decision, were filed too late and were not considered by the board. Accordingly, claims 3 and 4 cannot be reviewed or considered by this court.

> FN5. 35 U.S.C. s 112, second paragraph, states in relevant part:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In In re Hammack, 427 F.2d 1378, 1382, 57 CCPA 1225, 1231 (1970), we said:

> All provisions of the statute must be complied with in order to obtain a patent. The requirement stated in the second paragraph of section 112 existed long before the present statute came into force. Its purpose is to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with the adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection ***1227** involved and evaluate the possibility of infringement and dominance.

In the present case we find that the alternate expressions objected to by the board do not render the boundaries of the invention undeterminable. Claim 1 starts with "made entirely or in part of" which is to say "made at least partially of"; the phrase "one or several pieces" means the same as "at least one piece"; in the phrase "iron, steel or any other magnetic material" the words "iron" and "steel" are just examples of common magnetic materials. Similarly, the other alternate expressions in claims 1 and 2, although somewhat ungainly, nevertheless accurately determine the boundaries of protection involved. Perforce, the rejection of claims 1 and 2 under 35 U.S.C. s 112, second paragraph is reversed.

Reversed.

524 F.2d 1222, 187 U.S.P.Q. 664

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construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph. For example, claims which read: "The product produced by the method of claim 1." or "A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions ....." are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim. See also *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to "the nozzle of claim 7" in a method claim was held to comply with 35 U.S.C. 112, second paragraph. However, where the format of making reference to limitations recited in another claim results in confusion, then a rejection would be proper under 35 U.S.C. 112, second paragraph.

2173.05(g) Functional Limitations

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Whether or not the functional limitation complies with 35 U.S.C. 112, second paragraph, is a different issue from whether the limitation is properly supported under 35 U.S.C. 112, first paragraph, or is distinguished over the prior art. A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with 35 U.S.C. 112, second paragraph, was considered.

It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought. *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971).

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

2173.05(h) Alternative Limitations

I. MARKUSH GROUPS

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See *Ex parte Head*, 214 USPQ 551 (Bd. App. 1981); *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975); and *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). It is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931).

The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims indefinite or if it results in undue multiplicity, an appropriate rejection should be made.

Similarly, the double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. The mere fact that a compound may be embraced by more than one member of a Markush

group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, "selected from the group consisting of amino, halogen, nitro, chloro and alkyl" should be acceptable even though "halogen" is generic to "chloro."

The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. While in the past the test for Markush-type claims was applied as liberally as possible, present practice which holds that claims reciting Markush groups are not generic claims (MPEP § 803) may subject the groups to a more stringent test for propriety of the recited members. Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper.

Subgenus Claim

Genus, subgenus, and Markush-type claims, if properly supported by the disclosure, are all acceptable ways for applicants to claim their inventions. They provide different ways to present claims of different scope. Examiners should therefore not reject Markush-type claims merely because there are genus claims that encompass the Markush-type claims.

See also MPEP § 608.01(p) and § 715.03.

See MPEP § 803.02 for restriction practice re Markush-type claims.

II. "OR" TERMINOLOGY

Alternative expressions using "or" are acceptable, such as "wherein R is A, B, C, or D." The following phrases were each held to be acceptable and not in violation of 35 U.S.C. 112, second paragraph in *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975): "made entirely or in part of"; "at least one piece"; and "iron, steel or any other magnetic material."

III. "OPTIONALLY"

An alternative format which requires some analysis before concluding whether or not the language is indefinite involves the use of the term "optionally." In *Ex parte Cordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language "containing A, B, and optionally C" was considered acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim. A similar holding was reached with regard to the term "optionally" in *Ex parte Wu*, 10 USPQ2d 2031 (Bd. Pat. App. & Inter. 1989). In the instance where the list of potential alternatives can vary and ambiguity arises, then it is proper to make a rejection under 35 U.S.C. 112, second paragraph, and explain why there is confusion.

2173.05(i) Negative Limitations

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).

A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in